

**Request
For
Continued Examination (RCE)
Transmittal**
Address to:
Mail Stop
Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Application Number 09/528,978
Filing Date 3/21/2000
First Named Inventor OBACH, R.S.
Art Unit 1617
Examiner Name JIANG
Attorney Docket Number PC10244A USA

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 CFR 1.114**

- a. ☐ Previously submitted
- i. ☐ Consider the amendment(s)/reply under 37 CFR 1.116 previously filed on _____
(Any unentered amendment(s) referred to above will be entered).
- ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- iii. ☐ Other: _____
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☒ Affidavit(s)/ Declaration(s)
- iii. ☒ Information Disclosure Statement (IDS)
- iv. ☐ Other: _____

2. **Miscellaneous**

- a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
- b. ☐ Other: _____

3. **Fees**

- The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
- a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. _____
- i. ☒ RCE fee required under 37 CFR 1.17(e)
- ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)
- iii. ☐ Other: _____
- b. ☐ Check in the amount of \$ _____ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (Print/Type) ANDREA DORICU Registration No. (Attorney/Agent) 47,532
Signature _____ Date 12/18/03

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Name (Print/Type) ANDREA DORICU
Signature _____ Date 12/18/03

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This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Box RCE, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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in the claims, the purpose of quinidine and ajmalacine is to inhibit CYP2D6, and not for "mediating oxidative biotransformation for the major clearance mechanism in humans" (Official Action, page 5, lines 4-6), as alleged by the Examiner. In contrast, (2S,3S)-2-phenyl-3-(2-methoxy-5-trifluoromethoxyphenyl)methylamino-piperidine is drug for which the major clearance mechanism in humans is CYP2D6 mediated oxidative biotransformation, and therefore has a different purpose from quinidine and ajmalacine. Thus, the instant case is distinguishable from *In re Kerkhoeven*, and therefore *In re Kerkhoeven* is not applicable to this case.

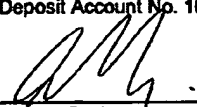
Applicants also submit a Declaration under 37 C.F.R. 132 by the inventor, Ronald Scott Obach, together with the data enclosed. As stated in the Declaration, in the enclosed data, Tables 1-4 describe enzymatic kinetic parameters for the metabolism of (2S,3S)-2-phenyl-3-(2-methoxy-5-trifluoromethoxyphenyl)methylamino-piperidine (including O-demethylation and N-dealkylation) in various mammals, and Table 5 describes the inhibition of the same compound by Cytochrome P450 isoform specific inhibitors. In the figures, Figures 10 and 11 show a correlation between metabolism and inhibition of the same compound using inhibitors quinidine (Figure 10) and ketoconazole (Figure 11). The foregoing data and figures show a surprising effectiveness of (2S,3S)-2-phenyl-3-(2-methoxy-5-trifluoromethoxyphenyl)methylamino-piperidine in combination with a CYP2D6 inhibitor such as, for example, quinidine or ketoconazole, further supporting the non-obviousness of the invention over the cited art.

In view of the foregoing, withdrawal of the rejection of Claim 1 under 35 U.S.C. 103(a) as allegedly obvious over Benet et al. and Hess (WO 96/14845) is respectfully requested.

In view of the amendments and remarks made herein, applicants respectfully solicit the issuance of a notice of allowance. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicant's undersigned attorney at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445.

Date: December 18, 2003


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